

with CZP in workplace and household productivity, and social participation were sustained up to 96 wks in PsA patients.

MUSCULAR-SKELETAL DISORDERS – Health Care Use & Policy Studies

PMS85

MARKET ACCESS OF IMPLANTABLE MEDICAL DEVICES - PART II: DECISION DRIVERS ACROSS GLOBAL MARKETS

Chawla AS¹, Tao C², Spinner DS³, Faulkner EC⁴, Doyle JJ⁵

¹Quintiles Consulting, Durham, NC, USA, ²Quintiles Consulting, Cambridge, MA, USA, ³Quintiles, Durham, NC, USA, ⁴Institute for Pharmacogenomics and Individualized Therapy, Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC, USA, ⁵Quintiles, Hawthorne, NY, USA
OBJECTIVES: With rising pressures on health care budgets, health technology assessment (HTA) agencies are increasingly scrutinizing medical devices (MDs) for economic benefits in addition to clinical benefits. This level of scrutiny has resulted in many unfavorable recommendations from agencies and only a small proportion of unconditionally favorable reviews. As an extension of our work reported at 2013 ISPOR Annual Congress (Dublin, IR) this study aims to: 1) Identify key criteria cited by HTA agencies as major decision drivers, 2) Note common criteria among reviews that were positive, negative, or positive with reservations, and 3) Analyze temporal or geographic trends among decision drivers. **METHODS:** A review of 68 HTAs and reimbursement decisions of implantable MD with a variety of indications was conducted, focusing on decisions published from 2008–2013 identified by Quintiles' HTA Watch from North America, Europe, and Australia. Clinical, economic, and other factors noted as pivotal to HTA and reimbursement decisions were registered and compared. Importantly, care was exercised to note only the criteria that triggered a HTA to make a favorable or unfavorable decision, as opposed to criteria that were only correlative. **RESULTS:** Key product attributes affecting HTA decisions include 1) sufficiency and quality of evidence, 2) cost offsets and budget impact, 3) adverse event profiles, and 4) comparison to existing alternatives where available. Notably, 33% of HTA decisions were negative, with many decisions citing insufficient evidence. Additionally, a majority of favorable HTA decisions were reserved in their recommendations, citing a need for additional evidence to uphold the initially favorable recommendation. The relative importance of economic considerations varied across countries. **CONCLUSIONS:** HTA agencies' scrutiny of sufficiency of evidence, among others, may significantly impact market access of medical devices. As such, manufacturers need careful planning to align evidence development, pricing and access plans with HTA agency, payer and pricing authority requirements.

PMS86

ANTI-TNF BIOSIMILARS INDICATED FOR RHEUMATOID ARTHRITIS ARE INCREASINGLY AVAILABLE IN EUROPE: HOW DO PAYERS AND KEY STAKEHOLDERS PERCEIVE THEM?

Sewak NPS, Jones C

Double Helix Consulting, London, UK

OBJECTIVES: The process of bringing a biosimilar to market in Europe is quicker, easier and cheaper than developing a new biologic. As a class, rheumatoid arthritis (RA) has the greatest number of anti-TNF biosimilar molecules in development, with more expected to follow. This research was focussed on the key issues reported by payers and Key Opinion Leaders (KOLs) in France, Germany and Italy. **METHODS:** Supported by secondary research our study entailed conducting one hour telephone interviews with influential senior payers involved in budgetary decision making at the national and regional level in addition to KOLs. These structured interviews explored how stakeholders perceived the introduction of anti-TNFs biosimilars. **RESULTS:** Payers see anti-TNF biosimilars as an opportunity to reduce the biologic budget but KOLs want to treat more patients within the same budget. Payers in Germany and France reported a greater perception of the efficacy of biosimilars than their counterparts in Italy. Treatment naïve patients are considered most suitable for anti-TNF biosimilars while automatic substitution was not favoured by any respondents. Nonetheless, price played a role and some KOLs stated they may attempt to switch existing patients who have a low risk of acute complications with very close monitoring. **CONCLUSIONS:** Biosimilars may be perceived unequally across markets. Manufacturers are likely to require the use of differentiated value stories when presenting their biosimilar products to payers and KOLs, with the latter more inclined to perceive them as an opportunity to treat more patients with the same expenditure instead of reducing budgets. Manufacturers will likely struggle to encourage the switching of existing patients onto biosimilars without offering a significant discount. In France and Germany, anti-TNF RA biosimilars are currently generating demand that closely matches their increasing prevalence.

PMS87

COMPARISON OF CLINICAL CHARACTERISTICS OF PATIENTS WITH RHEUMATOID ARTHRITIS (RA) RECEIVING BIOLOGIC MONOTHERAPY AND BIOLOGIC-CONTAINING COMBINATION THERAPY IN EUROPE

Narayanan S¹, Lu Y², Hutchings R², Baynton E²

¹Ipsos Healthcare, Columbia, MD, USA, ²Ipsos Healthcare, London, UK

OBJECTIVES: To assess the clinical characteristics of patients with RA who received biologic monotherapy ("Mono") or biologic-containing combination therapy ("Combo") in Europe. **METHODS:** A multi-country, multi-center medical chart review study of patients with RA was conducted in Q42012 among physicians in hospitals and private practices to collect de-identified data on patients who were recently treated with a biologic as part of usual care in France/Germany/Italy/Spain/UK. Physicians were screened for duration of practice (3–30yrs) and patient volume (≥ 2 RA biologic patients/week) and recruited from a large panel to be geographically representative in each country. Eligible patient charts (≥ 5) were randomly selected from among the patients visiting each center/practice during the screening period. Physicians abstracted date of diagnosis, treatment patterns/dynamics, and symptomatology/disease status. Mono and Combo patients were compared used descriptive statis-

tics. **RESULTS:** 1534 eligible RA patients were assessed; Mono: 428 (28%), Combo: 1106 (72%). Patient characteristics (Mono/Combo) included: age 51.8/51.7; female 71%/75%; weight 68.6/68.5kg; top three comorbidities: dyslipidemia (16%/19%), depression/anxiety (9%/13%), obesity (8%/12%). Time since diagnosis: 68.6/78.2mo. Current line of biologic therapy: first-line 86%/75%, second-line 11%/18%, \geq third-line 3%/6%. Top four biologics used across the two patient groups: etanercept (33%/adalimumab (30%)/tocilizumab (9%)/certolizumab pegol (7%). Current lab values/disease severity measures: ESR (mm/h) 21.7/23.2; CRP (mg/l) 10.3/10.3; rheumatoid factor (positive) 84%/87%; anti-CCP (positive) 70%/80%; current disease stage per physician judgment: mild 65%/52%, moderate 32%/40%, severe 3%/8%; mean VAS 3.4/3.6; mean HAQ 1.4/1.1; mean DAS 28 3.6/3.3; mean tender joint count 3.5/4.1; mean swollen joint count 2.4/2.6. **CONCLUSIONS:** In this cohort of RA patients in Europe, the majority of patients on monotherapy and combination therapy had mild disease per physician judgment and were on first-line biologic therapy. Lab measures and joint counts indicated only slightly higher disease burden among combination therapy patients. The impact of specific biologic treatments on observed patterns and the need for therapeutic sequencing may warrant further research.

PMS88

COPING WITH A NEW BIOLOGIC PARADIGM: PAYER STRATEGIES FOR THE PURCHASING OF COMPLEX BIOSIMILARS

Ziai Buetas A, Vidal Pinheiro A, Storer M

ICON, London, UK

OBJECTIVES: In Europe, biosimilars of complex molecules such as monoclonal antibodies have started to enter the market. In this research we aim to provide an understanding of the current expectations for the purchasing of these products as well as an overview of the tools that payers expect to employ to encourage biosimilar use. **METHODS:** Qualitative survey of payers across national, regional and local levels in France, Germany, Italy, Spain, the UK and Netherlands. Collection and analysis of data on (1) current and future attitudes relative to expected biosimilar purchasing systems; and (2) the tools that payers expect to use to drive biosimilar use, assuming this is a payer goal. **RESULTS:** (1) The method of biosimilar purchase in the short term will vary by country, with the majority of countries using tenders to procure these products; (2) While tenders restricting choice of product to a single winner will not be used extensively in the short term, these will be common across most countries in the future; (3) Payers will also use a number of other tools such as formal and informal recommendations, prescription incentives and auditing or prescription targets in order to encourage use of the product they have chosen; (4) New procurement pathways and tools are being developed to introduce biosimilars, as highlighted by the new biosimilar law in Italy which defines a level of discount at the national level. **CONCLUSIONS:** Payer strategies should maximize savings by introducing less expensive biosimilars, but also must consider physician preferences, especially when influenced by potentially valid concerns about lack of data. In order to do this, payers are creating novel purchasing frameworks and tools, and while they are currently reticent to use restrictive methods to encourage use of biosimilars, this is expected to rapidly change in a short timeframe.

PMS89

AN ASSESSMENT OF THE ASSOCIATION BETWEEN RURAL STATUS AND HEALTH SERVICE RESOURCE USE AMONG PATIENTS WITH ANKLE SPRAINS IN ONTARIO

Lucas GH, Bielska IA, Fong RK, Johnson AP

Queen's University, Kingston, ON, Canada

OBJECTIVES: Despite Ontario's universal health care system, differences exist in health care accessibility and quality across the province. The objective of this study is to assess health care resource utilization for patients with ankle sprains based on rurality. **METHODS:** Data on individuals who sought medical attention for ankle sprains between 2003 and 2011 in Ontario were obtained from multiple databases linked through the Institute for Clinical Evaluative Sciences (ICES). The Rurality Index of Ontario (RIO) was used to measure the rurality level of patients based on their population density and geographic distance to health care facilities. Demographic characteristics were obtained for each of five RIO categories. Health care utilization (number of visits to primary care physicians, specialists and ambulatory care) and physician billing costs were obtained and compared among the RIO categories. **RESULTS:** Between 2003 and 2011, the Ontario Health Insurance Program was billed \$64 million and \$36 million (2013 CAD) by specialists and general practitioners, respectively, for the treatment of ankle sprains and dislocations. Approximately \$116 million was spent on direct and indirect costs of emergency room visits for ankle sprains and dislocations. The largest proportion of rural injuries occurred in the top income quintile. Patients in the most rural RIO category saw specialists least often and had the highest number of ambulatory care visits. However, specialist visits constituted higher costs when compared to GP visits. The highest specialist costs found were for males, elderly patients, and those who sought medical attention during winter. The observed statistical differences in cost of GP visits across RIO categories were not clinically meaningful. **CONCLUSIONS:** The differences in health care utilization between RIO categories may indicate a lack of access to specialist care with those residing in rural areas relying on emergency departments for care. These results may be useful in allocating future resources to better serve rural patients.

PMS90

PREDICTING THE BURDEN OF KNEE ARTHROPLASTY REVISION OVER A 20-YEAR HORIZON

Comas M¹, Guerrero-Ludueña RE¹, Espallargues M², Coll M³, Pons M⁴, Sabatés S⁵, Allezpuz A², Castells X¹

¹IMIM (Hospital del Mar Medical Research Institute; Red de Investigación en Servicios de Salud en Enfermedades Crónicas (REDISSEC), Barcelona, Spain, ²Agència de Qualitat i Avaluació Sanitàries de Catalunya (AQuAS); Red de Investigación en Servicios de Salud en Enfermedades Crónicas (REDISSEC), Barcelona, Spain, ³Hospital de Mataró, Mataró, Spain, ⁴Hospital de Sant Rafael, Barcelona, Spain, ⁵Hospital Mútua de Terrassa, Terrassa, Spain